Iowa Department of Human Services

Kim Reynolds
Governor

Adam Gregg
Lt. Governor

Jerry R. Foxhoven
Director

November 15, 2017

W. Charles Smithson
Secretary of Senate
State Capitol Building
LOCAL

Carmine Boal
Chief Clerk of the House
State Capitol Building
LOCAL

Dear Ms. Boal and Mr. Smithson:

Enclosed please find copies of reports to the General Assembly relative to the Medicaid review of step therapy protocols in the prescription drug benefit decision making.

This report was prepared pursuant to the directive contained in 2017 Iowa Acts, Chapter 174, Section 12, subsection 25, as enacted in House File 653 (HF 653).

Please feel free to contact me if you need additional information.

Sincerely,

Merea Bentrott

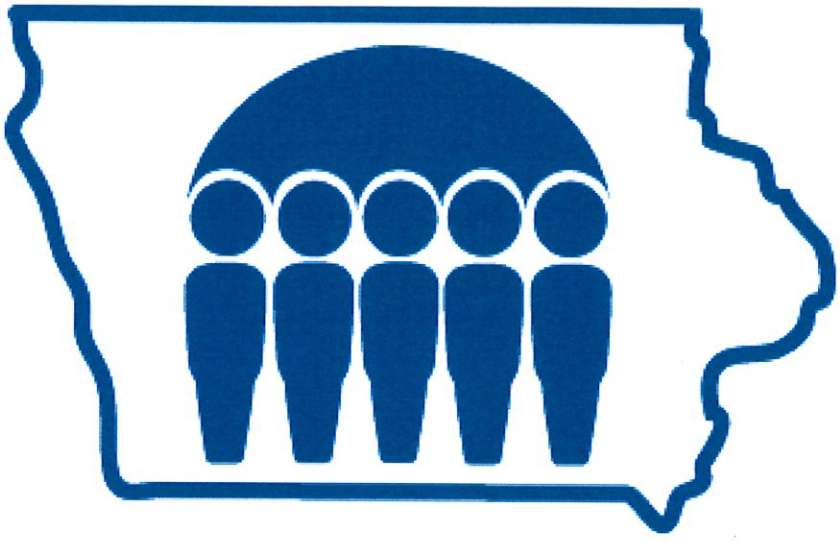
Merea D. Bentrott
Policy Advisor

MDB/slp/mbs

Enclosure

cc: Kim Reynolds, Governor

Iowa Department of Human Services



Medicaid Review of Step Therapy Protocols And Override Process

November 2017

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I. Executive Summary

Provisions of HF 653 enacted by the 87th General Assembly, directed the Department of Human Services (DHS) to review the use of step therapy protocols and override exceptions under the Medicaid program (pharmacy and medical benefits) for improving quality of life of members and increasing program efficiencies.

Step therapy is an integral component of the Medicaid pharmacy benefit under the legislatively mandated Preferred Drug List (PDL) and Prior Authorization (PA) programs. Step therapy is established in a transparent manner utilizing evidence-based clinical guidelines to ensure medically appropriate therapies are available to Medicaid members in a cost-effective manner.

Consistent with current state and federal regulations, exceptions to step therapy criteria are reviewed on an individual basis through the PA process with medical documentation from the prescriber. The process is efficient (twenty-four hours or less), transparent (PDL/PA criteria and forms are readily accessible anytime on the website), and well established (in place since 2005) while resulting in savings to the taxpayer funded program.

The Department recommends continuing the utilization of the existing Medicaid step therapy override processes established under the pharmacy benefit which meet the member's medical necessity requirements and contains costs within the Medicaid program.

In regard to step therapy under the medical benefit the Department recommends continued use of evidence-based medicine and clinical guidelines to direct medical therapy. This process considers outcomes to the member foremost, both in treating the underlying disorder and safety. The medications most frequently requested for exceptions to step therapy are often newer medications which lack the long history of experience by medical providers. Untoward side effects and long term side effects may be unknown, though found to be acceptable in short term research protocols presented for the Food and Drug Administration (FDA) approvals. Exceptions to step therapy are provided under the medical benefit when medical necessity can be demonstrated by the provider.

II. Introduction

Provisions of 2017 Iowa Acts, Chapter 124, Sections 1 and 2, as enacted in House File 233 (HF 233) added a new Iowa Code section 514F.7. This new section requires a health carrier subject to the insurance laws and regulations of the state, or subject to the jurisdiction of the commissioner, to follow the regulations regarding the use of step therapy protocols and override exceptions. The legislation set out numerous requirements that must be met if the health carrier, health benefit plan or utilization review organization utilizes step therapy.

Pursuant to HF 653, DHS is required to review and make recommendations regarding the use of step therapy protocols and application of step therapy override exceptions, as provided in HF 233, under the Medicaid program, while considering the potential for improving Medicaid member quality of life and increasing efficiencies under the program.

The Iowa Medicaid Enterprise (IME) staff in the pharmacy benefit, medical benefit and managed care policy areas collaborated with various entities to obtain input for this report. The pharmacy benefit area sought input from the Iowa Medicaid Drug Utilization Review (DUR) Commission and the Iowa Medicaid Pharmaceutical and Therapeutics (P&T) Committee, including the P&T clinical support staff. Both committee meetings also include a forum for public input. The medical benefit of IME has been reviewed by the Medical Director and the Clinical Advisory Committee (CAC). This committee is composed of Iowa physicians with active clinical practices across a variety of specialties. The committee meets quarterly in a preannounced meeting open to the public. The managed care bureau obtained input from the three contracted Medicaid managed care organizations (MCOs).

III. Program Overview

Background

HF 233 added a new section to the Iowa Code regarding the use of step therapy protocols, including definitions related to step therapy and identified an exception process that must be followed.

Specifically, the definitions and requirements included:

- *Step therapy protocol* means a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular covered person are covered under a pharmacy or medical benefit by a health carrier, a health benefit plan, or a utilization review organization, including self-administered drugs and drugs administered by a health care professional.
- *Step therapy override exception* is defined as a step therapy protocol that should be overridden in favor of coverage of the prescription drug selected by a health care professional within the applicable time frames and in compliance with the requirements specified in section 505.26, subsection 7, for a request for prior authorization of prescription drug benefits. This determination is based on a review of the covered person's or health care professional's request for an override, along with supporting rationale and documentation.
- *Establishment of step therapy protocols* indicates a health carrier, health benefit plan, or utilization review organization shall consider available recognized evidence-based and peer-reviewed clinical practice guidelines when establishing a step therapy protocol. Upon written request of a covered person,

a health carrier, health benefit plan, or utilization review organization shall provide any clinical review criteria applicable to a specific prescription drug covered by the health carrier, health benefit plan, or utilization review organization.

- *Step therapy override exceptions process transparency* indicates
  - a. When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier, health benefit plan, or utilization review organization through the use of a step therapy protocol, the covered person and the prescribing health care professional shall have access to a clear, readily accessible, and convenient process to request a step therapy override exception. A health carrier, health benefit plan, or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process used shall be easily accessible on the internet site of the health carrier, health benefit plan, or utilization review organization.
  - b. A step therapy override exception shall be approved by a health carrier, health benefit plan, or utilization review organization if any of the following circumstances apply:
    (1) The prescription drug required under the step therapy protocol is contraindicated pursuant to the drug manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:
      (a) Cause an adverse reaction to a covered person.
      (b) Decrease the ability of a covered person to achieve or maintain reasonable functional ability in performing daily activities.
      (c) Cause physical or mental harm to a covered person.
    (2) The prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person, such as the covered person's adherence to or compliance with the covered person's individual plan of care, and any of the following:
      (a) The known characteristics of the prescription drug regimen as described in peer-reviewed literature or in the manufacturer's prescribing information for the drug.
      (b) The health care professional's medical judgment based on clinical practice guidelines or peer-reviewed journals.
      (c) The covered person's documented experience with the prescription drug regimen.
    (3) The covered person has had a trial of a therapeutically equivalent dose of the prescription drug under the step therapy protocol while under the covered person's current or previous health benefit plan for a period of time to allow for a positive treatment outcome, and such prescription drug was discontinued by the

covered person's health care professional due to lack of effectiveness.
(4) The covered person is currently receiving a positive therapeutic outcome on a prescription drug selected by the covered person's health care professional for the medical condition under consideration while under the covered person's current or previous health benefit plan. This subparagraph shall not be construed to encourage the use of a pharmaceutical sample for the sole purpose of meeting the requirements for a step therapy override exception.

- The subsection on *limitations* indicates this legislation shall not prevent a health carrier, health benefit plan, or utilization review organization from requiring a covered person to try a prescription drug with the same generic name and demonstrated bioavailability or a biological product that is an interchangeable biological product pursuant to section 155A.32 prior to providing coverage for the equivalent branded prescription drug. Additionally, this section shall not prevent a health care professional from prescribing a prescription drug that is determined to be medically appropriate.

Iowa Medicaid Pharmacy Benefit

Pharmacy Benefit Step Therapy Protocols and Establishment

Pursuant to Iowa Code section 249A.20A, the DHS was required to implement a PDL under the pharmacy benefit of the Medicaid program based on recommendations from the P&T Committee. The PDL was implemented to ensure the list provides for medically appropriate drug therapies while achieving cost savings in the medical assistance program.

The PDL was implemented in 2005 and is a component of the PA process. While all drugs on the PDL are available, in order for reimbursement to occur, Iowa Medicaid requires that certain drugs must be approved beforehand. The goal of the PDL is to have as many cost effective drugs (both brand and generic) available as possible by encouraging manufacturers to participate in the process. Unlike commercial insurance plans, the net cost of a brand drug for Medicaid may be lower than the net cost of a generic due to federally required rebates. Drugs deemed to be clinically and/or economically superior to other clinically similar drugs are placed as preferred on the PDL and most can be prescribed and dispensed without a PA. As a result, the highest value medication to Medicaid (not just based on price but accounting for all financial and clinical impacts) is preferred. Non-preferred drugs on the PDL require a PA, with the primary criteria being documentation of previous trial and therapy failure with the preferred drug(s), unless evidence is provided that use of the preferred drug(s) would be medically contraindicated.

Initially, therapeutic drug categories excluded from the PDL were drugs prescribed for the treatment of human immunodeficiency virus or acquired immune deficiency syndrome, transplantation, or cancer and drugs prescribed for mental illness with the

exception of drugs and drug compounds that do not have a significant variation in a therapeutic profile or side effect profile within a therapeutic class. Effective January 2011, legislation eliminated the PDL exclusion of mental health drugs with the protections of grandfathering regimens established prior to January 1, 2011 and allowing a seven-day supply (rather than the standard three-day supply) while pending prior approval.

The current PDL process for all therapeutic categories on the PDL relies on recommendations based on evidence-based medicine where clinical efficacy and therapeutic effectiveness are vital to the selection process, as is the public forum in which these changes are discussed.

Aside from the requirements related to the PDL, clinical PA criteria as developed by the DUR Commission and based on evidenced based clinical practice guidelines and the FDA approval information, may require trial and therapy failure with other drugs before the requested agent would be approved.

The PDL and PA processes identified above may appear to fall under the definition of step therapy protocol as defined in HF 233. The establishment of these step therapy protocols through the Iowa Medicaid P&T Committee for the PDL recommendations, and the DUR Commission for the PA criteria recommendations, is through a transparent process at open public meetings. Additionally, all materials related to the Committee meetings are readily available on the respective websites and both Committees allow public input on agenda items through written and/or oral public comment. Finalized PDL drug status and detailed PA criteria are also posted on the website and shared with all Medicaid enrolled providers through the Informational Letter process, which notifies providers a minimum of thirty days in advance of the changes.

Both the fee-for service (FFS) and managed care programs follow the same PDL and PA criteria developed by the P&T Committee and DUR Commission respectively, which utilize evidence-based and peer-reviewed clinical practice guidelines in making their recommendations.

Pharmacy Benefit Step Therapy Override Exceptions Process

Through the Medicaid pharmacy PA process, consideration is already given to prescriber documented **contraindications to drugs** (HF 233, Section 1, subsection 3(b)(1)) as well as **prior therapies and failures** (HF 233, Section 1, subsection 3 (b)(3)), including while covered under a non-Medicaid benefit, that may be required under the PDL and/or PA criteria. Contraindications and a trial of a therapeutically equivalent dose of the drug are two circumstances under HF 233 where a step therapy override exception should be approved. Prescribers have been educated on and are very familiar with the existing Medicaid process, as these considerations are part of the PA criteria and forms. Additionally, call center staff are readily available to assist with any questions regarding coverage and PA form completion. **Documented adverse event/reaction** (HF 233, Section 1, subsection 3(b)(1)) to a drug is also mentioned in

the same subsection as contraindication and indicated to be a reason for a step therapy override exception. Adverse event/reaction is not defined in the legislation. While a medically documented adverse event is considered as part of the prior authorization review, the nature and degree of the reaction must represent a true contraindication to the required step.

Another circumstance for the exception approval under HF 233 is when the **prescription drug required is expected to be ineffective based on the clinical characteristics of the covered person** (HF 233, Section 1, subsection 3 (b)(2)), which includes adherence to or compliance with a plan of care, as determined by the health care professional. This would potentially allow a prescriber to deviate from evidence-based, peer reviewed clinical guidelines and/or FDA or compendia approved indications. As reflected in the Iowa Medicaid state plan and state administrative rules (441 Iowa Administrative Code (IAC) 78.2(4)), Iowa Medicaid can only reimburse for drugs that have a medically accepted indication, defined as an FDA approved or compendia supported indication. Additionally, services covered by Medicaid must be consistent with the diagnosis and treatment of the patient's condition, in accordance with standards of good medical practice, be required to meet the medical need of the patient for reasons other than convenience, and be the least costly type of service which would reasonably meet the medical need of the patient (441 IAC 79.9(2)).

While the subsection on **limitations** in the legislation clarifies it does not prohibit a health carrier, health benefit plan, or utilization review organization from requiring a trial of the same generic medication with the same bioavailability as the requested brand medication, it would preclude Medicaid from addressing issues of convenience related to dosage formulation. By specifying the generic medication must have the same bioavailability as the brand, it means a different release formulation or mechanism (such as immediate release, controlled release or extended release) of the same medication could not be required to be utilized if it has a different bioavailability. Many modified release formulations (with a different bioavailability) developed after the release of the original medication are more expensive than the original, without a clear clinical benefit. The PDL considers all clinical and cost impacts in the preference of the drug formulations and this language would be in direct conflict with the PDL process.

The fourth circumstance for the exception approval under HF 233 is when the person is **currently receiving a positive therapeutic outcome** for a medical condition on a specific prescription drug (HF 233, Section 1, subsection 3 (b)(4)), covered under the current or prior health plan benefit. It further states pharmaceutical samples should not be utilized for the sole purpose of meeting these requirements; however, this requirement will likely increase the promotion of brand drug sampling by the pharmaceutical manufacturers. Medicaid currently considers grandfathering, which allows established users to continue on a specific drug, through the PA process on a case by case basis. Additionally, as the P&T Committee makes status changes to drugs on the PDL, the review includes consideration of the necessity to grandfather existing users in specific circumstances. The current Medicaid PA criteria states that the use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will

not be considered when evaluating the medical condition or prior prescription history for drugs that require PA, as sampling was a mechanism utilized to bypass the PDL requirements.

If Medicaid was required to allow the HF 233 general concept of grandfathering all existing users, regardless of the medical condition and therapeutic category of the drug, there would be an overall increased cost impact to DHS related to product cost and/or rebates. Additionally, as part of the supplemental rebate agreement process, the expectation is those drug products not providing a supplemental rebate and in the same therapeutic category as the contracted drug, will be subject to a PA. Any change to that process could result in a decreased ability of the DHS to secure manufacturer participation through supplemental rebates.

While private insurance may utilize higher member copayment amounts for a non-preferred drug obtained through the step therapy override process to incentivize their members to follow their PDL and to offset the insurer's increased cost, Medicaid does not have the same option. Additionally, private insurers may also totally exclude[1] certain high cost drugs from coverage while Medicaid is required to cover all drugs that have a federal rebate agreement. However, Medicaid may prior authorize drugs. Therefore, attempting to replicate private insurer requirements for exceptions to step therapy within the Medicaid program can have significant policy and fiscal impacts.

FFS Pharmacy Benefit PA Process

Following submission of a PA request by a prescriber, notices of approval or denial are faxed to the provider and pharmacy within twenty-four hours from receipt of the completed request. The IME issues a notice of decision to the member within five working days of the date the prior approval form is returned to the provider, when a PA is denied. The member may file an appeal in accordance with 441 IAC Chapter 7. PA timelines as identified in Iowa Code section 505.26 would not be in compliance with the federally required Medicaid timelines.

An exception to policy may be utilized to request approval for a drug not otherwise covered by the DHS pursuant to 441 IAC Chapter 1.8. Exceptions to policy may be granted to the DHS rules, but they cannot be granted to rules that are based on federal policy or state law. An exception to policy is a last resort request and should only be requested after all administrative options have been exhausted. The request can be completed online on the DHS website or may be sent via mail, fax or email. Requests are acknowledged within seven days of receipt and a written decision is issued within one hundred and twenty days of receipt.

[1] CVS Health Announces 2018 Formulary Management Strategy. (2017, August 1). Retrieved from https://cvshealth.com/thought-leadership/cvs-health-announces-2018-formulary-management-strategy and Express Scripts 2018 National Preferred Formulary. (2017, July 31). Retrieved from http://lab.express-scripts.com/lab/insights/drug-options/2018-national-preferred-formulary.

Prescribers have been educated on and are very familiar with the DHS appeal and exception to policy processes. Call center staff are also available to assist in explaining the process. There is explanatory information and instructions on these two processes on the PDL website.

The research demonstrates that step therapy programs for therapy classes other than antipsychotics can provide significant drug savings through the greater use of lower-cost alternatives. The drug savings and clinical impact of step therapy for antipsychotics are inconsistent given the research conducted to date. Research also demonstrates step therapy programs for a select category provide significant drug savings without increasing use of other medical services. The research on step therapy does show variability in the breadth of evaluation and methodological quality as well as possible study bias. [2] Additional outcomes-based research will provide a more conclusive analysis of the clinical and fiscal impacts of step therapy programs on patients and health systems, including Medicaid. The judicious use of a PDL, including step therapy and active management, positively impacts both compliance and adherence, even in complex diseases such as hepatitis C.

Pharmacy Benefit Committees

The DUR Commission reviewed HF 233, in the context of the HF 653 review request and the current DHS process for step therapy overrides at their August 2, 2017, meeting[3]. The DUR Commission focused on Section 1, subsection 3(b) as it was most applicable to the Commission. Below are the comments/concerns of the DUR Commission:

- The development of Medicaid Pharmacy prior authorization (PA) criteria is currently a transparent process conducted in open public meetings with several opportunities for written and oral public comments.
- Item 3(b)(1-3) Circumstances to allow Step Therapy Exceptions - The current Medicaid Pharmacy PA process generally covers the circumstances described in this section as allowed by Medicaid regulations and allows for exceptions to step therapy requirements using clinical judgment with proper medical documentation from the prescriber.
- Item 3(b)(2) Prescription drug is expected to be ineffective – It is unclear how patient adherence could be evaluated ahead of time. Predicted non-compliance should not be an exception and members should be required to try preferred medications first. While prescribers attempt to simplify patient regimens, it should not be the primary driving force for selecting a prescription drug. After much discussion, the Commission felt this entire section should be stricken as it creates a loophole for everyone and completely undermines the concept of the Preferred Drug List (PDL) and PA criteria.

[2] Motheral B.R. "Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature," J Manag Care Pharm. 2011;17(2):143-55.
[3] Iowa Medicaid Drug Utilization Review Commission. (2017, August 2).August 2, 2017 Meeting. Retrieved from https://iadur.org/minutes.

Overall, the DUR Commission feels there is no need to change the current PDL and PA process to accommodate a step therapy protocol. There are current processes in place to allow for the types of step therapy exceptions detailed in HF 223 consistent with Medicaid regulations and implementing this protocol would undermine the concept of the PDL and PA criteria.

The P&T Committee reviewed HF 233, in the context of the HF 653 review request and the current DHS process for step therapy overrides at their August 17, 2017 meeting[4]. The P&T Committee agreed that the current process is both transparent and allows Medicaid members access to medically necessary treatments.

The P&T clinical support staff analyzed the financial impact of HF 233, in the context of HF 653 and estimated a $2.5-3 million total annual cost impact to the Medicaid program if the program were required to replicate HF 233 requirements. The increase in prescription drug costs was estimated based on the requirement to exempt drugs from step therapy which would result in a lower market share shift to the most cost-effective Medicaid drugs. The fiscal impact factors in the loss of national rebates as well as the loss of supplemental rebates which manufacturers offer to have their products in a preferred position on the PDL.

Iowa Medicaid Medical Benefit

Step therapy evolved from studying the efficacy and side effects of one drug over another. For the most part, these studies do not include the costs of the drugs. Much of the information generated is paid for by the pharmaceutical industry and published in peer reviewed medical journals. Reliable studies require the result of the study to be reproducible. This process allows the medical prescriber to choose the drug which has a predictable outcome and predictable safety profile. Diversions from step therapy protocols under the medical benefit are allowed when medical necessity is demonstrated by the provider and as compassionate allowances.

The CAC did not recommend a diversion from step therapy. The committee anticipated an increase in pharmacy expenses to Medicaid and possibly unnecessary risks to members with the abandonment of step therapy. Continued review of protocols for new medications has been advocated by the committee to address new drugs and review of new studies on existing drugs. Members who receive medication as an exception under the current process, are strongly encouraged to participate in a study protocol when it is appropriate. Bypassing established recommendations and treatment protocols with new medications may provide significant medical knowledge but only if evaluated systematically. New oncology medications are routinely evaluated in this fashion evaluating safety and side effects, tumor response, and dose.

The cost to IME on the medical benefit for removal of step therapy has not been calculated or estimated, but would be expected to increase. Several of the newer

[4] Iowa Medicaid Pharmaceutical & Therapeutics Committee. (2017, August 17).August 17, 2017 Meeting. Retrieved from http://www.iowamedicaidpdl.com/pt_committee_info.

medications released tend to be more expensive medications and may have efficacy in managing a member's medical condition. Once a medical condition is controlled with one medication, there is little impetus to try a less expensive medication which may also be efficacious, unless the member has a financial stake in coverage, as with most private insurers. It was pointed out by one CAC member, that if payment for medication was the sole responsibility of the member, as was the case 50 years ago, step therapy would not be challenged, in fact it would be demanded by members. The CAC found no compelling reason to recommend a change in that rationale when IME is the payor.

Iowa Medicaid Managed Care Benefit

The three Medicaid managed care organizations also reviewed HF 233, in the context of the HF 653 regarding the step therapy protocols and override exceptions process and provided the following analyses.

AmeriHealth Caritas' (ACIA) positions regarding projected impact are as follows:

1. Related to the Pharmacy Benefit
    - HF 233, Section 2. Establishment of step therapy protocols - This provision replicates the functions of the already existing DUR Commission for Iowa Medicaid. It is redundant, but as long as it refers to the existing committee and does not create a parallel entity, it should not be harmful. Clinical criteria are widely available for public consumption, both by Iowa Medicaid and ACIA.
    - HF 233, Section 3. Exceptions Process Transparency - ACIA believes this to already be contemplated within the current PA process, and that it is already readily accessible and easy to use.
        - (b)(1) - ACIA feels a contraindication to a step therapy drug is already contemplated in the clinical review process for prior authorizations
        - (b)(1)(a)-(c) - Language has the potential to be negatively financially impactful to the Medicaid program without providing true added clinical value to the patient population. Use of vague terms (what is the definition of "adverse reaction"), broad sweeping assumptions and highly subjective terms (physical or mental harm) of possible adverse effects are heralded as valid conclusions of appropriate pharmaceutical care vs evidence based clinical proof of a true medical contraindication to a preferred step therapy agent or providing objective, evidence based medical care. True medical contraindications to preferred step therapy agents are already contemplated in the prior authorization review process. A recommendation for improvement on this language could include the Food and Drug Administration (FDA) MedWatch form be used as the definition of "adverse reaction".
        - (b)(2)-(4) - The Iowa Medicaid DUR Commission and the P& T Committee already consider best medical practice standards in development of prior authorization criteria and drug status on the PDL. While the clinical review process via prior authorization takes into consideration prior established therapy, current therapeutic outcomes,

continuity of care, and peer reviewed medical literature in support of medical necessity decisions related to drug therapy, federal guidelines still restrict the ability to approve medication therapy for uses/diagnoses which are not FDA approved or supported by an acceptable compendia source. Sub point (4) does have significant potential for Medicaid program impact. While ACIA understands that a person is receiving positive benefit on their drug this does not simultaneously prove that the PDL preferred agent won't provide that same benefit. This clause would effectively eliminate all grandfathering which means even when the IME makes changes to the PDL all members would remain on current therapy because they are "receiving a positive therapeutic outcome." This would inhibit the State's ability to move market share to a new preferred agent when fiscally appropriate.

- (c) and (d) - No impact expected as current contractual agreements are in line or better than these timeframes, and the covered medications are defined by the State.
- (e) - No impact expected, as these guidelines are already in practice as part of the prior authorizations process. Internal appeals for pharmacy still have the ability to elevate to yet another level of review via the State Fair Hearing process.

- HF233, Section 4. Limitations – The only concern is that this language may not be written broadly enough to encompass biosimilars.

The potential financial impact based on the most liberal assumptions being taken with the language in this legislation, meaning any non-preferred product on the PDL would have the potential to be granted an "exemption" from current step therapy requirements merely based off provider preference and non-evidence based assumption, would be in the range of a $2 -10 million impact. Again, this is a rough estimate and ACIA is only able to compare existing PA data to come to this figure.

2. Related to the Medical Benefit - ACIA had our Utilization Management (Medical) Department review this, and they had no comment. Our UM Department does not perform PA reviews on enough medications at this time for this to create a significant fiscal impact for them.

Amerigroup's (AGP) positions regarding projected impact are as follows:

1. Related to the Pharmacy Benefit
   A. Clinical - By having no restrictions, Iowa Medicaid will result in providers potentially using a more expensive drug first line which in some cases may not be appropriate according to the clinical guidelines.

   B. Fiscal - The fiscal impact of removing the PDL, PA criteria, quantity limits, etc. would be $41.5 million.

2. Related to the Medical Benefit – AGP does not use step therapy for medical drug benefit management.

UnitedHealthcare's (UHC) positions regarding projected impact are as follows:

1. Related to the Pharmacy Benefit - UHC has estimated the impact of HF 653, which would remove step therapy protocols and preferred drug status for medications administered to Medicaid Managed Care enrollees in Iowa. UHC's analysis suggests that the provisions of this legislation would result in a substantial increase in pharmacy costs of roughly $40 million annually. Currently, 6 percent of overall utilization of pharmacy claims are for drugs currently deemed non-preferred. Our analysis assumed that this ratio would increase to the greater of 15 percent or the current ratio for each drug class. The analysis did not apply class-specific assumptions, any class with a non-preferred rate currently under 15 percent was set to 15 percent. In practice, there will be some drug classes where drug utilization will increase more than 15 percent, and some drug classes that will be less. The proposed impact analysis is an estimate based on many unknown assumptions. The increase to the Iowa Medicaid program proposed by this legislation could be largely underestimated in this analysis.

2. Related to the Medical Benefit - Since step therapy protocols are not applied to the medical benefit (no point of sale adjudication), the assessment by UHC is that the evaluation of medical necessity for medical injectables will remain relatively unchanged. There would be marginal increases in medical costs, but not materially substantial.

IV. Conclusions/Recommendations

Iowa Medicaid Pharmacy Benefit

Under the pharmacy benefit, the DHS has established transparent processes through the PDL and PA program and exception to policy to consider medically necessary step therapy overrides as defined in HF 233. The PDL and PA processes utilize step therapy to ensure members get the right treatment at the right time, and if there's a more affordable alternative (brand or generic) to Medicaid, the member has access to the preferred medication first. When there are specific reasons where a prescriber indicates a different drug may be advised through medical necessity documentation, the DHS already applies appropriate consideration to step therapy overrides in compliance with state and federal regulations. Therefore, to replicate all aspects of HF 233 step therapy override exceptions within the Medicaid program would not result in increased efficiencies or necessarily improve the quality of life for Medicaid members. However, if the step therapy override exceptions in HF 233 were required to be replicated by Medicaid, the process as defined in the legislation would undermine the integrity of the PDL and PA program. Additionally, pharmacy costs would increase and the DHS may be noncompliant with certain aspects of state and federal regulations.

The recommendation is to continue utilizing the existing Medicaid step therapy override processes established under the pharmacy benefit which meet the member's medical necessity requirements and contains costs within the Medicaid program.

Iowa Medicaid Medical Benefit

The recommendation is to continue the use of step therapy within the medical benefit to be consistent with the delivery of cost efficient medical care. Prescribing practices without a scientific basis i.e. off-label use, is strongly discouraged by the CAC. Concerns expressed by the CAC regarding the allowance of exceptions to step-therapy include: the lack of an established safety profile for these new medications, the potential for prescribing a new medication outside of the indication(s) studied, and the prescribing influence of the pharmaceutical industry through their marketing practices. The CAC providers recommend continuing to follow FDA approved indications, specialty society guidelines, and published best practices in management of medical care for Medicaid members, which includes the utilization of step therapy.